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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,511	09/17/2003	Thomas William Rademacher	1012E-910001US	9184

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,511	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *20-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 20-22, drawn to a method of treating diabetes with P- and A-type inositolphosphoglycans (IPG), classified in class 514, subclass 23.

II. Claims 20-22, drawn to a method of treating diabetes with a P-type IPG, classified in class 514, subclass 23.

III. Claims 20-22, drawn to a method of treating diabetes with an A-type IPG antagonist, classified in class 424, subclass 130.1.

IV. Claims 23 and 24, drawn to a method of treating obese type II diabetes with a P-type IPG, classified in class 514, subclass 23.

V. Claims 23 and 24, drawn to a method of treating obese type II diabetes with an antagonist of an A-type IPG, classified in class 424, subclass 130.1.

VI. Claims 23 and 24, drawn to a method of treating obese type II diabetes with both a P-type IPG and an A-type IPG antagonist, classified in class 424, subclass 141.1.

VII. Claims 25-26, drawn to a method of treating type I diabetes with a P-type IPG and an A-type IPG, classified in class 514, subclass 23.

VIII. Claims 25-26, drawn to a method of treating lean type II diabetes with a P-type IPG and an A-type IPG, classified in class 514, subclass 23.

IX. Claims 27 and 28, drawn to a composition of a P-type IPG, classified in class 514, subclass 23.

X. Claims 27 and 28, drawn to a composition of an antagonist of an A-type IPG, classified in class 424, subclass 141.1.

XI. Claims 27 and 28, drawn to a composition of a P-type IPG and an antagonist of an A-type IPG, classified in class 424, subclass 141.1.

XII. Claims 29 and 30, drawn to a composition of a P- and an A-type IPG, classified in class 514, subclass 23.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions IX-XII and I-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the compositions of Groups IX-XII could be used in methods of detecting the presence of type I diabetes, lean type II diabetes and obese type II diabetes, rather than in the claimed methods of treating these diseases in Groups I-VIII.

3. Inventions I-VIII are different methods that treat different diseases. Obese type II diabetes, type I diabetes and lean type II diabetes are different diseases that have distinct etiologies, clinical manifestations, therapeutic endpoints, and patient populations. As such, methods used to treat these different diseases use distinct products and process steps, making them patentably distinct.

4. Inventions IX-XII are different products that differ in structure. Pharmaceutical compositions comprising a P-type IPG, a P-type with an A-type IPG, an antagonist of an A-type IPG, and a P-type IPG with an A-type IPG antagonist have different structures that give rise to distinct functional properties. As such they are patentably distinct.

5. The inventions of Groups I-XII are distinct for the reasons given above. Additionally, Groups I-XII are distinct because the prior art searches required for Groups I-XII are not necessarily of overlapping scope. For example, art disclosing a composition consisting of a P-type IPG and an A-type IPG does not necessarily read on a composition that consists solely of a P-type IPG or a composition that consists solely of an A-type IPG. Similarly, methods of treatment using a composition consisting of a P-type IPG and an A-type IPG need not read as prior art on a method of treatment using only P-type IPG or only an A-type IPG. Therefore, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 14, 2004

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